

Post Market Monitoring of Cold Chain Equipment

A How-to-Guide to Sentinel Surveillance

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Contents

1. Introduction		3
	1.1.	3
	1.2.	3
	1.3.	3
	1.4.	4
	2.	5
	2.1.	5
	2.2.	5
	2.3.	5
	2.4.	6
3. Implementing Sentinel Surveillance		7
<i>Phase 1:</i>		
	3.1.	8
	3.2.	8
	3.3.	9
	3.4.	9
	3.5.	9
	3.6.	10
<i>Phase 2:</i>		
	3.7.	12
	3.8.	13
	3.9.	13
	3.10.	15
	3.11.	16
	4.	17
	5.	18

1. Introduction

1.1. Introduction to Post Market Monitoring of cold chain equipment

Post Market Monitoring (PMM) of immunization cold chain equipment (CCE) refers to the collection and analysis of equipment performance data from health and storage facilities to enable corrective and preventive action leading to improved CCE performance.

To date there has been no systematic and central mechanism to monitor equipment deployed to countries, and this gap in performance feedback from country immunization systems can cause poor equipment design or performance to go unnoticed and unaddressed by WHO and equipment manufacturers. Given the importance of CCE to achieve immunization coverage and equity goals, there is a strong need to strengthen PMM so that CCE issues can be adequately addressed.

A PMM Working Group¹, tasked with guiding activities and aligning global efforts around strengthening PMM, was set up in 2018. The group identified sentinel surveillance as one of the ways to collect standardised performance data at the country level and address the gap in quality feedback on equipment performance. The approach was piloted in four countries, DRC, Haiti, Pakistan and Bangladesh in 2020-2021².

1.2. Who this guide is for

This guidance is aimed at the implementing entity for PMM at the country level. This would primarily be the ministry of health and the national immunization programme manager, but can also include development partners or other local organisations.

1.3. How to use this guidance document

This document is intended to guide country stakeholders planning to introduce PMM through the set up and implementation of sentinel surveillance. The guidance is primarily aimed at ministries of health and national immunization programme managers as well development partners or other local organisations in cases where they are the implementing entity.

The guidance focuses on two key steps:

- II. **set up and**
- III. **implementation.**

For each step the document describes the **key activities**, provides links to available **tools and resources** and refers to **best practice tips** gathered from pilot country experience.

¹ The working group, chaired by WHO Product, Quality and Safety (PQS), currently has representatives from WHO (PQS and EPI teams), UNICEF (Programme and Supply Divisions), the Bill and Melinda Gates Foundation, the Gavi Secretariat, PATH, the Clinton Health Access Initiative, as well as independent experts

² See **Annex 9** for detailed lessons learned from the country pilots

The guidance is not intended to be prescriptive, but rather provide examples, tools and general direction on how [PMM](#) can be implemented most effectively.

1.

1.4. Glossary of terms & acronyms

CCE	Cold Chain Equipment
CCIS	Cold Chain Information System, an online data collection tool
EPI	Essential Programme on Immunization
Failure analysis	Procedure to identify the causes(s) of cold chain equipment failure
Fridge Tag	A high precision temperature data logger for the continuous monitoring of sensitive vaccines and pharmaceuticals stored in medical refrigerators & freezers
Immunization coverage	Percentage of individuals in a target group who have received all the recommended vaccines for their age.
MoH	Ministry of Health
MoU	Memorandum of Understanding
NIP	National Immunisation Programme
Non-functional equipment	Equipment is considered non-functioning if certain thresholds are crossed in the monthly reported temperature data. A report of non-functionality triggers further failure analysis to identify the cause and should not on its own be used as an indication of fridge performance.
PMM	Post-market monitoring
PMM indicators	A set of 10 key indicators to be reported on monthly for each of the CCE included in the surveillance. If certain thresholds are met the equipment is deemed non-functional until failure analysis can determine the cause.
Routine reporting	Monthly reporting of indicators from health facilities
Sentinel surveillance	Methodology used primarily in infectious disease data collection. A sentinel surveillance site is a single or small number of health facilities that are responsible for collecting data. In contrast, with population-based surveillance, every appropriate health facility reports on predefined diseases with the goal of identifying all cases in a specific geographic area.
WhatsApp	Online instant messaging application
Zero reporting	Reporting of not only the presence but also the absence of cases, this ensures that participants have not merely forgotten to report.
WHO PQS	Product, Quality and Safety Team at WHO headquarters which prequalifies products and devices so that member states and UN purchasing agencies are assured of their suitability for use in immunization programs

2. Sentinel Surveillance of cold chain equipment

2.1. Why Sentinel Surveillance



The [sentinel surveillance](#) approach has been selected for [PMM](#) as it is a tried and tested data collection method. It is both **rapid** and **cost effective** and when well implemented can yield **high quality results**. The relatively small investment in time and resources, coupled with a low reliance on technology at the country level, means that the approach is more likely to be sustainable in the long term.

2.2. Methodology

Building on existing country systems and needs, a list of [sentinel surveillance](#) sites is selected for routine monitoring of cold chain performance. The surveillance consists of monthly [zero reporting](#) from the sites (Section 3.4), based on a standard set of [indicators](#) (Annex 3). The [routine reporting](#) (Section 3.7) is coupled with regular site visits, accompanied whenever possible by [NIP CCE](#) technicians, to verify data and follow up on findings. A key component of the approach is [failure analysis](#) (Section 3.9), which is carried out if the [routine reporting](#) indicates non-functioning equipment. The [failure analysis](#) aims to conclude whether the reported non-functionality is due to a equipment performance issue (i.e. design fault) or other causes (i.e. power fluctuations or human error).

2.3. Data ownership and sharing

The collection of [CCE](#) performance data through [sentinel surveillance](#) serves a dual purpose. At the global level, data collected from [sentinel surveillance](#) sites will provide the WHO Product, Quality and Safety (PQS) Team, which prequalifies products and devices so that member states and UN purchasing agencies are assured of their suitability for use in immunization programs, with comprehensive and consistent data giving important insight into the reasons for equipment failure. The information can inform equipment specifications and verification protocols, as well as feed into timely feedback to manufacturers to enable corrective and preventative actions. At the country level the systematic collection of performance data and [failure analysis](#) provides valuable information that can be used to improve countries' vaccine management systems.

The key principle guiding the use and sharing of [PMM](#) data is that all data is owned by countries. With country approval, WHO PQS takes on the role of custodian of data and its analysis at the global level. WHO will share aggregated, non-country specific analysis with partners, and more broadly through an annual [PMM](#) Report available on the WHO website.

2.4. Tools

A set of tools has been developed to support countries in setting up and managing [sentinel surveillance](#) of [CCE](#).

Tool	Use in PMM	Timing
Site selection criteria	Guidance on how to select the sentinel surveillance sites. See Annex 2	During the Set-up Phase
PMM Indicators	A set of 10 key indicators to be reported on monthly for each of the CCE included in the surveillance. If certain thresholds are met the equipment is deemed non-functional until failure analysis can determine the cause. See Annex 3	Training during Set Up Phase , active use during Implementation Phase
PMM Taxonomy	Recommended terms and definitions to describe CCE parts and failures. See Annex 1	Throughout PMM work
Follow up and failure analysis questionnaire	A set of questions to guide the follow up and failure analysis when CCE has been identified as non-functional See Annex 4	Training during Set Up Phase , active use during Implementation Phase
Cold Chain Information System	Application for managing cold chain equipment, including inventory and maintenance. The application includes a data collection function for the PMM indicators and the follow up and failure analysis. See Annex 6 for guidance on how to access, set up and use the application	Training during Set Up Phase , active use during Implementation Phase

3. Implementing Sentinel Surveillance

Phase 1: Setting up a Surveillance System

The first of the two major phases of Sentinel Surveillance programmes concerns setting up the system. The following table provides an overview of the key parameters of set-up: who needs to be involved, the duration of the phase, outputs and the relevant tools and resources required to support the set-up. (Refer to section 4 of this guide for a full list of links to the tools and resources.) Thereafter this section of the guidance deep-dives into human resources, how to select surveillance sites, developing a budget and workplan, setting up zero reporting, selection, set up and training on the data collection tools and establishing roles and responsibilities.

Phase 1 objective: Prepare for successful PMM sentinel surveillance		
	Who should be involved?	<ul style="list-style-type: none"> • Senior Ministry of Health (MoH) staff • Senior implementing organisation staff (if other than MoH) • PMM Surveillance Officer (once hired) • Local NIP staff (officials, health centre, technicians)
	Duration	Approximately 3 months
	Outputs	<ul style="list-style-type: none"> • Signed MoUs or agreements (as necessary) • Budget and workplan • Site visit plan • Final list of sentinel surveillance sites with up to date inventory • CCIS X set up for data collection • Health centre staff trained on data collection and reporting • Technicians at central and local level trained and sensitized • Local NIP authorities sensitized
	Tools and resources (see section 4 of this guide)	<ul style="list-style-type: none"> • Site selection criteria • PMM Sentinel Surveillance Scope of Work • Sentinel Surveillance Officer ToRs • PMM Indicators • CCIS application and guidance

3.1. Human resources

The hiring of a [PMM](#) Surveillance Officer is a key first step in the **Set-Up Phase**. The Surveillance Officer's profile and required experience is described in [Annex 7](#). The Officer should be a proven project manager, experienced in cold chain, vaccine management and temperature monitoring procedures, with a good understanding of the national immunisation system. Experience of cold chain equipment maintenance is a plus.

Lessons from pilots show that the management of [PMM](#) is a full-time role, but as it combines both project management and technical skills, it might sometimes be better shared by two officers; one responsible for management and coordination, and the other responsible for the technical aspects.

Throughout the implementation of [Sentinel Surveillance](#), input will also be needed from [NIP](#) staff, especially local technicians and staff at the participating health facilities (see section 3.6 for details on recommended roles and responsibilities across the different actors). Once roles and responsibilities within [NIP](#) have been agreed, contracts or [MoUs](#) may be needed to ensure full participation.

Pilots have shown that a successful set up phase requires leadership and involvement from senior MoH staff to ensure that there is full buy-in for all the elements of the planned [Sentinel Surveillance](#).

3.2. Selecting surveillance sites

[Annex 1](#) describes the criteria for consideration when selecting surveillance sites, as well as the recommended number of sites. The selection of sites should not be random: the sites selected should include equipment from a range of manufacturers and a mix of easy and hard to reach areas, as well as well performing and low performing areas and health system levels. When selecting sites, the willingness and ability of local staff to participate should be considered. Sites should be selected in close collaboration with national and regional [NIP](#) programme staff using existing inventory, deployment and installation data. In some cases a sign off on the final list of sites from the MoH may be needed.

Box 1: Cold chain inventory as a data source

Lessons from pilot countries show that the available inventory of cold chain equipment is often incorrect or not fully up to date and cannot be used on its own as a source of information for the selection of sites. During the **Set-up Phase** it is important to visit all the sites initially selected, update the inventory and, if needed, revisit and revise the list of sites to better reflect the reality on the ground.

3.3. Developing a budget and work plan

The pilots have demonstrated that the key budget lines for PMM are:

1. human resources,
2. training for surveillance set-up and
3. transportation to and from site visits.

Depending on the country context the cost of [NIP](#) technicians accompanying the Surveillance Officer on site visits for [failure analysis](#) will need to be fully budgeted to ensure their participation and, in some cases, a small stipend may be necessary to ensure timely and quality reporting from health centre staff.

The budget and workplan should plan for routine site visits with at least two planned visits per year to each site, ensuring participation of [NIP](#) technicians/staff whenever possible. The plan should also include funds for ad-hoc site visits when failures have been detected. Depending on the number of sites being monitored these could be up to 1-2 visits a month.

3.4. Setting up zero reporting from surveillance sites

Lessons from pilot countries show that a successful set-up ideally involves an initial visit to each of the sites to review and update the available inventory in the [CCIS](#) data management tool and check the availability and functioning of [FridgeTags](#) (see **Box 2** and [Annex 8](#)).

Box 2: FridgeTag as the source of reported temperature data

To ensure comparability of the data collected it is recommended that the monthly temperature data reported through PMM is read from a FridgeTag. An essential step in the set-up of the Surveillance System is therefore to ensure that all the monitored CCE have a functioning FridgeTag device and health centre staff are trained on their correct use. Detailed guidance on the use of FridgeTags is available in [Annex 8](#).

In-person training for regional and health facility staff is also preferable, to introduce the [PMM](#) concept and [indicators](#), reporting templates, data collection tools and reporting frequency. This can either be done through individual visits or regional workshops where staff across sites are grouped together.

3.5. Selection, set up and training on the data collection tools

The [CCIS](#) application is the recommended data collection tool for [PMM](#) but depending on the local context it might be more appropriate for some or all sites to report using [WhatsApp](#) or a simple excel sheet (see [Annex 6](#)). In cases where the reporting sites are not using [CCIS](#) it is still recommended that all data be inputted into [CCIS](#) at the central level.

Lessons learned from pilots show that in-person training of health facility staff on the data collection tool is more effective than remote training sessions. Lessons from pilots have also highlighted that, irrespective of which tool is used, there is a need to also collect monthly [FridgeTag](#) PDF read outs to allow for verification of the reported temperature data.

- CCIS set up and training:** [CCIS](#) is a comprehensive tool for the management of inventories and cold chain equipment. The application, that can be uploaded on to any Android smartphone, also includes the PMM [indicators](#) for routine monthly reporting as well as questionnaires for [failure analysis](#) follow up.
 - ☑ *Detailed guidance on how to set up CCIS as well as training materials is available in [Annex 10](#).*
- Other tools:** Where the use of smartphones for reporting is not appropriate, a simple paper-based word or excel template can be used for reporting. One of the pilot countries used [WhatsApp](#) successfully to collect photos of paper-based reports filled in at the health facilities.
 - ☑ *Examples of templates can be found in [Annex 6](#).*

3.6. Establishing roles and responsibilities

Roles and responsibilities of all stakeholders from the health facility through to the national programme, as well as relevant development partners, should be clearly defined at the start.

Stakeholder	Recommended role in PMM
Ministry of Health	Data ownership, analysis and use to improve national vaccine management systems.
NIP Manager	Oversight of the PMM work at the country level, follow up when failures are identified.
Sentinel Surveillance Officer	Day to day management of PMM: routine data collection, site visits, follow up, failure analysis, reporting to MoH and the regional immunisation programme.
NIP Technicians	Analysis of the causes of failure and maintenance.
Regional EPI	Oversight of PMM work at the regional level, follow up when failures are identified.
Health Centre Staff	Monthly reporting of the PMM indicators.
Partner Organisation(s)	Support to MoH. If implementer of PMM, oversight of PMM work.

WHO HQ Geneva	Custodian of global level data and analysis, improvements of equipment specifications and feedback to manufacturers.
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If [PMM](#) is implemented by an entity outside of the MoH there is a need to establish an agreement or [MoU](#) with the national authorities for the setting up of the [sentinel surveillance](#) sites and monitoring system. The [MoU](#) should include agreement on the sites selected, [indicators](#) to be monitored, workplan for surveillance activities and roles and responsibilities of designated government focal points.

Phase 2: Managing Routine PMM Surveillance

Routine surveillance and follow up can start once a Surveillance Officer has been hired, [sentinel surveillance](#) sites selected, all participating [NIP](#) staff trained and sensitised and the necessary documentation finalised and approved. This section of the guidance provides an overview of how to manage sentinel surveillance programmes. The table below provides an overview of key parameters: who needs to be involved, outputs and required tools and resources. (Refer to section 4 of this guide a full list of links to the tools and resources.) Thereafter, this section covers monthly reporting, routine site visits, follow-up and failure analysis, reporting to authorities and the quarterly in-country review of findings.

Phase 2 objective: Ensuring successful routine surveillance and follow up		
	Who should be involved?	<ul style="list-style-type: none"> • PMM Surveillance Officer • Local immunisation programme staff (officials, health centre, technicians) • National Immunisation Programme Manager • Partner Organisation(s) (as relevant) • WHO HQ Geneva
	Outputs	<ul style="list-style-type: none"> • Complete monthly reports from all surveillance sites • Failure analysis reports (as required) • Aggregated quarterly reports (as required)
	Tools and resources (see section 4 of this guide)	<ul style="list-style-type: none"> • CCIS application and guidance • Excel version of monthly questionnaire and failure analysis questionnaires (Follow up and Failure analysis templates) • Quarterly reporting slide deck template

3.7. Monthly reporting from sentinel sites

The Surveillance Officer should compile data on the 10 [PMM indicators](#) from sentinel sites each month. Reporting formats depend on the capacity at each site i.e. [CCIS](#), email, paper, [WhatsApp](#) or whichever is most appropriate. The Officer will also collect [FridgeTag](#) PDF read outs to allow for verification of the reported temperature data. If the data is reported in another format the Officer will then input the data into the [CCIS](#) application.

Note: [FridgeTags](#) keep a record of temperature data for 60 days. It is therefore possible to collect routine data bi-monthly. However, bi-monthly reporting risks failures going unreported and uninvestigated for longer.

3.8. Routine site visits

The Surveillance Officer should carry out routine surveillance visits each month to selected sites based on the workplan. Each site should be visited at least twice a year. The purpose of the routine visits is to improve the completeness of reporting and provide supportive supervision and feedback.

3.9. Follow up and failure analysis

Monthly reporting will indicate if there is non-functioning equipment at any of the sentinel sites. Equipment is considered non-functioning if any of the following thresholds are met in the reported temperature data:

- 5 or more heat alarms in a month
- 1 or more freeze alarms in a month
- 1 or more heat alarms with duration of 48h or more in a month

When non-functioning equipment is reported, a two-step process is recommended to identify the cause of the failure. The Surveillance Officer starts by carrying out the **'Follow up'** procedure, which is then followed by the full **'Failure Analysis'** procedure, if needed.



Box 3: Temperature thresholds and the definition of ‘non-functional’

For the purposes of PMM, equipment meeting the temperature data thresholds where vaccines are at risk should be reported as ‘non-functioning’ in the monthly PMM report. Thresholds are defined as the following:

5 or more heat alarms in a month:

Rationale: 5 or more heat alarms might be a result of a door left open, excessive loading of fridge (or similar operational issues) as well as malfunction due to unidentified faults. While at this stage the cause is not known, vaccine quality is at risk and the equipment should be reported as **Not functional**.

1 or more freeze alarms in a month:

Rationale: A single freeze event can lead to loss of potency of all vaccines in a fridge. Should this arise the equipment should be reported as **Not functional**.

1 or more heat alarms with duration of 48h or more in a month:

Rationale: As above while at this stage the cause is not known, vaccine quality is at risk and the equipment should be reported as **Not functional**.

It is important to note that a report of ‘non-functionality’ should not be used on its own as an indicator of equipment performance or malfunction.

An initial report of ‘non-functionality’ triggers further failure analysis to identify the cause which can include programmatic issues (i.e. door left open), external issues (i.e. power fluctuations) and performance issues (i.e. thermostat fault.)

● Follow up procedure

The follow-up procedure is a short questionnaire that can be conducted remotely over the phone with health facility staff and does not require any technical knowledge or tools. The responses can be recorded in an Excel sheet (see [Annex 4](#) for the template) or recorded directly into [CCIS](#). The purpose of the Follow up procedure is to determine if a technician visit is needed or if immediate cause(s) of failure can be identified and address by health facility staff or the Surveillance Officer without a technician. If the failure cause is known after completing the Follow up procedure, the component that failed and the failure cause(s) should be recorded in the Failure Reporting section of the data collection tool.

- **Failure analysis procedure**

The failure analysis is a detailed questionnaire that can only be conducted on site by a trained cold chain technician with a set of tools. The responses can be recorded in an Excel sheet (see [Annex 4](#) for the template) or recorded directly into [CCIS](#). The purpose of the [failure analysis](#) procedure is to identify the cause(s) of failure which could not be identified or resolved during the Surveillance Officer's initial follow-up. Once identified, the component that failed and the failure cause(s) should be recorded in the Failure Reporting section of the data collection tool.

Note: Even when the Surveillance Officer has the technical background to carry out a full [failure analysis](#) alone, lessons from the pilot countries point to the importance of always involving the relevant local technical staff both for their expertise and ability to follow up on identified failures.

Note: Lessons from the pilot countries highlight the importance of swiftly repairing equipment and resolving problems following reporting and [failure analysis](#). This is not only good practice in vaccine management, but also helps to ensure continued regular reporting from health facility staff who see immediate actions resulting from their participation in PMM.

Box 4: Three causes of failure

Performance Issues (i.e. faulty thermostat)
Programmatic Issues (i.e. fridge door left open) and
External Issues (i.e. power fluctuations).

Failures due to Programmatic or External factors can usually be identified using only the Follow up procedure, to fully investigate Performance Issues the Failure Analysis procedure is needed.

3.10. Reporting to national authorities and WHO

[PMM](#) data is owned by the country and the raw data set should be accessible to MoH at all times. If PMM is implemented by an entity outside of the MoH, basic analysis and key findings should be made available to MoH for review on a monthly basis.

With country approval, the WHO PQS team takes on the role of custodian of data and its analysis at the global level. Each month, participating countries share the raw PMM data, [FridgeTag](#) PDF files and failure analysis findings with the PQS team.

3.11. Quarterly in-country review of findings

Surveillance Officer convenes key technical national and/or regional cold chain staff and other relevant stakeholders on a quarterly basis to review the data and [CCE](#) performance issues identified, and to discuss necessary mitigation actions. Lessons from pilot countries show that regular review meetings with key stakeholders are especially important when PMM is being implemented by development partner organisations.

4. Tools & Resources

<p>Annex 1. Site selection criteria What: Criteria for selecting PMM site Who: PMM implementer When: during the set-up phase</p>
<p>Annex 2. PMM Indicators What: A set of 10 key indicators to be reported monthly for each of the CCE included in the surveillance. If certain thresholds are met the equipment is deemed non-functional. Who: Sentinel Surveillance Officer/reporting health facility staff When: during monthly reporting</p>
<p>Annex 3. PMM Taxonomy (English and French) What: Recommended terms and definitions to describe CCE parts and failures. Who: Sentinel Surveillance Officer/technicians When: During failure analysis</p>
<p>Annex 4. Follow up and Failure Analysis Questionnaire/Methodology What: A set of questions to guide the follow up and failure analysis Who: Sentinel Surveillance Officer/technicians When: When CCE has been identified as non-functional</p>
<p>Annex 5. PMM Sentinel Surveillance Pilot-Lessons Learned from implementing countries What: Summary of key lessons from the three PMM pilot countries Who: PMM implementer When: during set up phase training and sensitisation</p>
<p>Annex 6. Excel template for PMM indicator reporting from health facilities What: Excel version of the indicator reporting template Who: Sentinel Surveillance Officer/ reporting health facility staff When: during monthly reporting</p>
<p>Annex 7. Sentinel Surveillance Scope of Work and Sentinel Surveillance Officer ToR What: Scope of work and terms of reference Who: PMM implementer When: during the set-up phase hiring of Sentinel Surveillance Officer</p>
<p>Annex 8. FridgeTag Guidance (English and French) What: Guidance on the use of FridgeTags Who: Sentinel Surveillance Officer/health facility staff When: during set up phase and initial health facility visit and training</p>

Annex 9. PMM Sentinel Surveillance training slide deck**What:** Slides outlining the PMM Sentinel Surveillance Guidance**Who:** PMM implementer**When:** during set up phase training and sensitisation**Annex 10. CCIS Guidelines: *PENDING*****What:** Guidelines on how to set up and use the CCIS X application**Who:** Sentinel Surveillance Officer/ reporting health facility staff/technicians**When:** during monthly reporting and failure analysis

5. Contacts and further support

WHO PQS Post-market monitoring pqspmm@who.intCCIS Helpdesk: **forthcoming**